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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/251,638	02/17/1999	HENRY DANIELL	922.6641P	3456

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/10/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/251,638

Applicant(s)

DANIELL, HENRY

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The substitute specification, the amendment to the specification, the amendments to claims 1 and 3-5 and the addition of new claims 8-10 have been entered, as requested in Paper No. 14, filed 18 September 2002.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The drawings are objected to for the reasons indicated on the accompanying form PTO 948. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

Response to Amendment

4. The rejections of claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by John et al (1996, Proc. Natl. Acad. Sci. USA 93:12768-12773) and John (1997, US Patent 5,602,321) and of claims 1, 3 and 5-7 under 35 U.S.C. 102(b) as being anticipated by John et al (1997, US Patent 5,597,718) in light of John et al (1995, Plant Physiol. 108:669-676) is WITHDRAWN in light of amendments to the claims to recite that the gene or coding sequence encodes a protein comprises at least one pentapeptide that is repeated at least once, wherein the gene or coding sequence does not occur in nature.
5. The rejections of claims 1-7 under 35 U.S.C. 103(a) as being unpatentable over John et al (1997, US Patent 5,597,718) in view of Zhang et al (1996, Plant Cell Rep. 16:174-179) and over John et al (1996, Proc. Natl. Acad. Sci. USA 93:12768-12773) in view of Zhang et al, 1996

Art Unit: 1638

(*supra*) is WITHDRAWN in light of amendments to the claims to recite that the gene or coding sequence encodes a protein comprises at least one pentapeptide that is repeated at least once, wherein the gene or coding sequence does not occur in nature.

Specification

6. The substitute specification filed 18 September 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: the introduction of paragraph 8.1, the introduction of the last line of paragraph 0014 and "tobacco" in lines 6 and 7 of that paragraph and the word "elasticity" in the last line of paragraph 7, the repositioning of paragraph 10.1, and the deletion of paragraph 15 and the first part of paragraph 8 (all paragraph numbers are from the marked-up copy of the specification).

Applicant is required to cancel the new matter in the reply to this Office Action.

7. The amendment filed 18 September 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: the deletion of paragraph 14 and the substitution in its place of another version of paragraph 12.

Applicant is required to cancel the new matter in the reply to this Office Action and resubmit the original paragraph 14.

Response to Amendment

8. The objection to claims 2, 4 and 7 because of informalities is WITHDRAWN in light of amendments to or cancellation of the claims.

9. The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, detailed in the Office action of 11 March 2002, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is WITHDRAWN in light of amendments to or cancellation of the claims.

Claim Objections

10. Claim 10 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 already seems to indicate that the pentapeptide is GVGVP; thus claim 10 does not further limit claim 8.

Claim Rejections - 35 USC § 112

11. Claims 1, 3-5 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 March 2002, as applied to claims 1-7. Applicant's arguments filed 18 September 2002 have been fully considered but they are not persuasive.

Art Unit: 1638

Applicant urges that the amended claims and substitute specification provide an enabling description that would teach one of skill in the art how to perform the instant invention, without a deposit of the plasmids. Applicant urges that the teaching of a nucleic acid encoding GVGVP is not required because it was taught in Daniell et al, 1997, and offers to copy the sequence into the specification, because the article was incorporated by reference. Applicant urges that it is the expression of GVGVP in a cotton plant that is the instant invention, not the GVGVP or a nucleic acid that encodes it (response pg 6-8).

This is not found persuasive. The support for the sequence in the specification is cryptic, and the specification lacks direction to a particular reference. The nucleic acid sequence is not well-known in the art because it was hidden in references that was not clearly related to the disclosed invention, and the sequence is not clearly disclosed in the specification. Applicant should file a continuation-in-part to incorporate the essential material.

Additionally, claims 3-5 are drawn to expression cassettes that encode a repeated pentapeptide. Thus, the instant invention is a nucleic acid that encodes the pentapeptide.

Lastly, the specification does not provide guidance for all nucleic acids that encode a protein comprises at least one pentapeptide that is repeated at least once, wherein the nucleic acid does not occur in nature.

Again, it is suggested that Applicant enable the invention by deposit of plasmids pBI121-X2-120mer and pBI121-E6-HW-120mer, as detailed in the previous Office action. Note that such a deposit will not enable all nucleic acids encoding GVGVP or multimers of that polypeptide, nor will it enable nucleic acids encoding any elastic and plastic protein based polymer. It will only enable plasmids pBI121-X2-120mer and pBI121-E6-HW-120mer.

Art Unit: 1638

12. Claims 1, 3-5 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 March 2002, as applied to claims 1-7. Applicant's arguments filed 18 September 2002 have been fully considered but they are not persuasive.

Applicant urges that the teaching of a nucleic acid encoding GVGVP is not required because it was taught in Daniell et al, 1997, and offers to copy the sequence into the specification, because the article was incorporated by reference. Applicant urges that it is the expression of GVGVP in a cotton plant that is the instant invention, not the GVGVP or a nucleic acid that encodes it (response pg 6-8).

This is not found persuasive because the instant specification has not taught cotton plants whose fiber cells have been transformed with a DNA encoding an elastic and plastic polymer. The specification states that one method (particle bombardment) of cotton transformation requires undue experimentation to carry out (pg 6), and the other (*Agrobacterium*-mediated) can only be carried out on certain cotton cultivars. The specification fails to teach these cultivars, and the claims fail to reflect this limitation.

13. Claims 1, 3-5 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 11 March 2002, as applied to claims 1-7. Applicant's arguments filed 18 September 2002 have been fully considered but they are not persuasive.

Art Unit: 1638

Applicant urges that the teaching of a nucleic acid encoding GVGVP is not required because it was taught in Daniell et al, 1997, and offers to copy the sequence into the specification, because the article was incorporated by reference. Applicant urges that it is the expression of GVGVP in a cotton plant that is the instant invention, not the GVGVP or a nucleic acid that encodes it (response pg 6-8).

This is not found persuasive. The support for the sequence in the specification is cryptic, and the specification lacks direction to a particular reference. The nucleic acid sequence is not well-known in the art because it was hidden in a single reference that was not clearly related to the disclosed invention, and is not clearly disclosed in the specification. Applicant should file a continuation-in-part to incorporate the essential material.

Additionally, just because one of skill in the art could readily envision nucleic acids that encode these proteins does not mean Applicant possessed nucleic acids that function in the claimed cells. See *Fiddes v. Baird* (BdPatApp&Int) 30 USPQ2d 1481, which states “knowledge of [the] amino acid sequence of [a] protein, coupled with [the] established relationship in genetic code between [a] nucleic acid and [the] protein it encodes, would not establish inventor’s possession of [a] gene encoding that protein”.

Lastly, the specification does not teach a representative sample of all nucleic acids that encode a protein comprises at least one pentapeptide that is repeated at least once, wherein the nucleic acid does not occur in nature.

14. Claims 1, 3, 5 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1638

Neither the instant specification nor the originally filed claims appear to provide support for the phrase “a gene encoding an amino acid sequence including at least one pentapeptide that is repeated at least once which gene does not occur in nature” in claim 1, “a coding sequence encoding an amino acid sequence including at least one pentapeptide that is repeated at least once which coding sequence does not occur in nature” in claim 3, and “The transgenic cotton plant of claim 1, wherein said gene encodes between 20-251 repeats of the amino acid sequence Gly-Val-Gly-val-Pro (SEQ ID NO:2)”. Thus, such phrases constitute NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrases or to cancel the new matter.

15. Claims 1, 3-5 and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 1 is indefinite in its recitation of “which gene does not occur in nature” and claim 3 is indefinite of its recitation of “which coding sequence does not occur in nature”. As all genes and coding sequences that occur in nature have not been sequenced, what sequences are excluded are unknown, and the metes and bounds of the claim are not clear.

It is not clear in claim 3 if the coding sequence is part of expression cassettes or not, as the cassette appears to only comprise a terminator, one or more selectable marker genes, one or more regulatory elements and a promoter.

16. Claims 1, 3-5 and 8-10 are free of the prior art, given the failure of the prior art to teach a cotton plant transformed with a gene or coding sequence that encodes a protein comprises at

Art Unit: 1638

least one pentapeptide that is repeated at least once, wherein the gene or coding sequence does not occur in nature and given the failure of the prior art to teach an expression cassette for transformation of such plants, wherein the cassette comprises a fiber-specific promoter.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.
December 5, 2002



AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
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